REMARKS/ARGUMENTS

Applicants gratefully acknowledge the courtesy shown by Examiner Fronda in the telephonic interview with Paul Fehlner and the undersigned of Darby & Darby on October 13, 2004. During the interview the utility rejections under 35 U.S.C. §§ 101 and 112, first paragraph; the written description rejections under 35 U.S.C. § 112, first paragraph; the indefiniteness rejection under 35 U.S.C. § 112, second paragraph; and the anticipation rejections under 35 U.S.C. § 102(b) were discussed. Pursuant to the interview, Applicants include below arguments in support of their positions on these issues.

Claims 1-8, 18 and 22-33 have been withdrawn. Claims 11, 12 and 21 have been canceled without prejudice. Claims 9-10, 12-17 and 19-20 are under consideration. Claims 9 and 20 have been amended.

Support for the claim 9 amendment "expressed only in cardiac and skeletal muscle" can be found in the specification at page 8, lines 1-5. Support for the claim 9 amendment "comprises about 285 amino acids" can be found in the specification at page 7, lines 15-16. Support for the claim 9 amendment "shares about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:4" can be found in the specification at page 7, lines 21-23. Support for the claim 20 limitation "wherein the stringent conditions are hybridization at 68°C in 0.2XSSC or 42°C in 50% formamide, 4XSSC" can be found in the specification at page 18, lines 17-20.

Claim Objections

Claims 12, 20 and 21 have been objected to because the claims recite non-elected subject matter, i.e., SEQ ID NO:3. Claim 12 has been canceled. Claims 20 and 21 have been amended to exclude SEQ ID NO:3. Accordingly, the objections should be withdrawn.

Rejection under 35 U.S.C. §101

The Examiner has maintained the rejection of claims 9-17 and 19-21 under 35 U.S.C. §101 as not supported by a credible asserted utility or a well established utility. During the telephonic interview, the Examiner indicated that he would review Applicant's argument, as set forth below, on utility with the supervising examiner for this application.

As set forth in the Amendment filed April 30, 2004 (pages 7-8), the claimed Ozz nucleic acids have at least three credible asserted utilities (e.g.,, for making Ozz protein, which in turn is useful for preparing antibodies for the detection of conditions associated with muscle damage such as myocardial infarction; as a research reagent to identify drugs that recognize the Ozz gene or protein and, thereby, target muscle tissue). One such utility, which was emphasized in the October 13, 2004 interview, is the use of Ozz nucleic acids for making recombinant Ozz protein, which in turn is useful as an antigen for the preparation of antibodies. Such antibodies are useful for the diagnosis of a disease state, e.g., galactosialidosis. Galactosialidosis is a disorder of glycoprotein metabolism, which can affect, for example, the heart and result in severe hypotonia (i.e., loss of muscle tone) (specification, page 44, lines 1-4). Autopsy studies of normal hearts using anti-mouse Ozz antibodies have shown that Ozz protein is confined to the region surrounding the nucleus in atrial cardiac muscle cells. In galactosialidosis, however, Ozz protein has an abnormal distribution pattern and level (specification, page 44, lines 4-9). Thus, galactosialidosis can be diagnosed by detecting an abnormal distribution of Ozz protein in a patient's heart cells using anti-Ozz protein antibodies. The use of Ozz nucleic acids to produce recombinant Ozz protein, which in turn serves as an antigen for the production of anti-Ozz protein antibodies, is a specific and substantial utility. See specification, page 34, lines 11-12 ("altered Ozz protein levels and localization can be detected

to diagnose diseases associated with altered Ozz protein expression and localization"). Although Ozz protein has additional utilities, this showing of one credible utility is sufficient to meet the requirement of 35 U.S.C. § 101. See, *Raytheon v. Roper,* 724 F.2d 951, 958 (Fed. Cir. 1983), *cert denied,* 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. 101 is clearly shown.").

Accordingly, the claimed Ozz nucleic acids have specific and substantial utility and this rejection should be withdrawn.

Rejection under 35 U.S.C. §112, First Paragraph, Enablement

The Examiner has maintained the rejection of claims 9-17 and 19-21 under 35 U.S.C. §112, first paragraph because, according to the Examiner, the claimed invention is not supported by either a credible asserted utility or a well established utility and, therefore, one skilled in the art would not know how to use the claimed invention.

A lack of utility rejection under 35 U.S.C. §101 also creates a rejection under 35 U.S.C. §112, first paragraph. See *In re Brana,* 51 F.3d 1560 (Fed. Cir. 1995). However, a lack of utility rejection under 35 U.S.C. §112, first paragraph should not be imposed or maintained unless an appropriate basis exists for imposing the lack of utility rejection under 35 U.S.C. §101. See MPEP 2107.01(IV). The remarks in the section immediately above point out the utility of the claimed invention under 35 U.S.C. §101 as disclosed in the specification. Since the invention is useful, the rejection under 35 U.S.C. §112, first paragraph, enablement should be withdrawn.

Rejection under 35 U.S.C. §112, First Paragraph, Written Description

Claims 20-21 have been rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not conveyed in the specification as to reasonably convey to one skilled in

the art that the inventor, at the time the application was filed, had possession of the claimed invention. To address this rejection, claim 20 has been amended to include the transitional phrase "consisting," as suggested by the Examiner, and has been further amended to include specific hybridization conditions. Claim 21 has been canceled.

Accordingly, the Examiner should withdraw this rejection.

Rejection under 35 U.S.C. §112, Second Paragraph

Claim 20 has been rejected under 35 U.S.C. §112, second paragraph, as indefinite because, according to the Examiner, the specific stringent hybridization conditions and the specific nucleotide sequence/structure of the "PPCA exon Ia" has not been recited. Claim 20 has been amended to include the limitation "wherein the stringent conditions are hybridization at 68°C in 0.2XSSC or 42°C in 50% formamide, 4XSSC." The Examiner indicated in the October 13, 2004 interview that the rejection based on the absence of a SEQ ID NO corresponding to the nucleotide sequence of the PPCA exon Ia exon would be withdrawn because it was known in the art.

The structure of PPCA exon Ia was known. For example, see Rottier et al., DNA Cell Biol. 1997;16(5):599-610 ("Rottier") (specification, page 4, lines 17-25). Rottier discloses: "mouse exon Ia position 11-30, GGAATTCGATGCGCAGATAGGGTTCAA-3'" (Rottier, page 600, 2nd column, 2nd full paragraph).

Accordingly, the rejection under 35 U.S.C. §112, second paragraph should be withdrawn.

Rejection under 35 U.S.C. §102(b)

The Examiner has maintained the rejection of claims 9-11 under 35 U.S.C. §102(b) as anticipated by Nakamura et al., Oncogene 1998;16(8):1009-19 ("Nakamura"). The Examiner

interpreted the claims to encompass any nucleic acid encoding any protein involved in development and function of muscle with homology with Drosophila *neu.*

Amended claim 9 recites that the isolated nucleic acid encodes an Ozz protein having an amino acid sequence of about 285 amino acids, which is expressed only in cardiac and skeletal muscle. Nakamura discloses a gene encoding 557 amino acids (Nakamura, page 1014, first full paragraph). Further, the protein disclosed in Nakamura is expressed in brain and astrocytoma tissue (Nakamura, page 1012, first paragraph).

Accordingly, claims 9-11 are not anticipated by Nakamura and this rejection should be withdrawn.

Rejection under 35 U.S.C. §102(b)

Claim 20 has been rejected under 35 U.S.C. §102(b) as anticipated by Lee et al. According to the Examiner, this reference discloses "a nucleic acid which is expected to hybridize to SEQ ID NO: 1 because no specific hybridization conditions have been recited." Amended claim 20 has been amended to recite high stringency conditions, i.e., hybridization at 68°C in 0.2XSSC or 42°C in 50% formamide, 4XSSC. Thus, only oligonucleotides having the highest degree of sequence similarity will hybridize to the claimed isolated nucleic acid. There is no expectation that the 644 nucleic acid sequence disclosed by Lee et al. will hybridize under stringent conditions to a nucleic acid of SEQ ID NO:1.

Accordingly, this rejection should be withdrawn.

Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

By _____

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